



THE MARSHFIELD
NEUROSCIENCES

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May 25, 1999

Linda Hu, M.D.
Dockets Management Branch
Food and Drug Administration
5630 Fisher's Lane Room 1061 HFA-305
Rockville, MD 20850

RE: Docket #76N-052N

Dear Mr. Rothschild:

As discussed with you on the phone the other day, there is an error of labeling of practically all over-the-counter cold and allergy preparations. This specifically refers to the drug interaction precaution which reads "Do not use this product if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions or Parkinson's disease), or for two weeks after stopping the MAOI." As a specialist in neurology with a large Parkinson's disease practice, this labeling has resulted in undue worry, concern and perhaps even health care risks for individuals with Parkinson's disease. Reading this label, many patients and families will forego using and over-the-counter cold/allergy/flu preparation in the belief that they may be at risk by using such a medication. The result is individual patients suffering not just the symptoms at hand (be it congestion, cough, and so forth) but possibly secondarily placing themselves at risk for developing something more serious like a bronchial pneumonia because they did not use a simple OTC medication. Although I cannot provide any substantiating evidence, it is not inconceivable to think that there may be elderly patients with Parkinson's disease who go on to

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develop significant morbidity and possibly even mortality from an upper respiratory infection that might have been "nipped in the bud" were they not scared away from using an OTC preparation.

The facts are as follows:

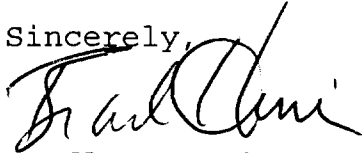
1. The vast majority of patients with Parkinson's do not use an MAO (monoamine oxidase) inhibitor.
2. There is only one MAO inhibitor used in Parkinson's disease, i.e., Selegiline (also known as Deprenyl and Eldepryl).
3. Eldepryl is a MAO Type B inhibitor. At the doses used in Parkinson's disease (5 to 10 mg daily) it has absolutely no effect on MAO type A.
4. MAO-A inhibitors have been closely linked to a chemical reaction known as "the tyramine" or "cheddar cheese" affect. Briefly stated, patients taking an MAO inhibitor (such as potent antidepressant medications like Nardil and Trandate) are at risk for developing hypertensive crisis if they take in medications or foods high in "amine" content. Decongestant preparations (for example, those containing pseudoephedrine, phenylpropanolamine and others) contain amines; thus, individuals already taking an MAO-A inhibitor should not use concomitantly these over-the-counter preparations (thus, the drug interaction labeling for MAO-A inhibitors in depression is absolutely correct).
5. Eldepryl has nothing to do at all with these types of medications, unless an overdose occurs. In my 12 years of practice at a large multispecialty clinic with literally thousands of patient interactions using Eldepryl and Parkinson's disease, I have never seen or had an overdose occur. Nor have I (or any other movement disorder/neurology specialist to my knowledge) ever had to deal with a hypertensive crisis due to Eldepryl use in a patient with Parkinson's disease.

In summary, I hope you can appreciate the fact that this is a non-existent drug interaction, that the mislabeling is causing significant confusion (and not just among patients, but also with pharmacists and other health care professionals) and that, in the end, it is the patient population that is suffering.

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Feel free to contact me at any time if I can be of further assistance. I think it is only fair to let you know that this issue is sufficiently important that I will be very likely taking it to the media in the near future.

Sincerely,

A handwritten signature in black ink, appearing to read "Bradley C. Hiner". The signature is fluid and cursive, with a large initial "B" and "H".

Bradley C. Hiner, M.D.
Department of Neurology

BCH:jag

CC: Mr. Kerry Rothschild
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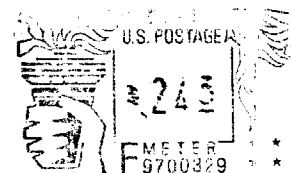
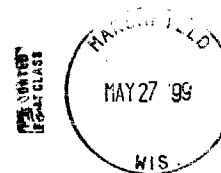


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RETURN SERVICE REQUESTED



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